I hereby certify that this correspondence is being deposited with the U.S. Postal Service "Express Mail Post Office to Addressee" service, Label EL 530 373 662 US, under 37 CFR 1.10 on:

Date: 2-9-0(

By: Debora L Scockneyer

ATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Manz, et al.

SERIAL No.: Not yet Assigned

FILED: Concurrently Herewith

FOR: METHOD FOR CONTROLLING SAMPLE

INTRODUCTION IN MICROCOLUMN

SEPARATION TECHNIQUES AND

SAMPLING DEVICE

Examiner: Unknown

ART UNIT: Unknown

STATEMENT REGARDING PREEXAMINATION SEARCH IN CONNECTION WITH PETITION TO MAKE SPECIAL

Assistant Commissioner of Patents Washington, D.C. 20231

Sir:

I, Larry W. Thrower, an authorized agent in the above-identified application, hereby declare that I have made a pre-examination search according to MPEP \$708.02, section VIII, which satisfies the search requirement for accelerated examination. This search did not reveal any art that would anticipate or render obvious the claimed subject matter.

A. Applicant's Claimed Invention

The present invention, as embodied in newly presented Claim 19, is directed to a method for electrokinetically injecting and moving a geometrically defined sample volume along an electrolyte channel.

B. Search by Authorized Agent

The U.S. Patent Claims database file 340 in Dialog was searched for patent claims containing the word "sample" within 2 words of any form of the word "inject". The search was limited to patents in all subclasses of classes 204 and 453, and published prior to 1995. Fifty patents were returned that met the criteria described above. However, an examination of the abstract and exemplary claim of each patent revealed that none of the patents appeared to anticipate or render obvious the claimed device.

C. References Cited in Related U.S. Applications

Enclosed herewith are copies of the Information Disclosure Statements and accompanying Forms-1449 submitted during the course of prosecution of the U.S. patent application upon which this case claims priority. Copies of the references were previously submitted in the priority application, U.S. Patent Application Serial No. 08/226,605.

Respectfully submitted,

Larry Throm

Larry W. Thrower

Registration No. P47,994

CORRESPONDENCE ADDRESS

Customer No. 22918 (650) 324-0880

Date: 2-9-01

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Date: 2-9-01

By: Debord Brockmayer

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Manz, et al.

SERIAL No.: Not yet Assigned

FILED: Concurrently Herewith

FOR: METHOD FOR CONTROLLING SAMPLE

INTRODUCTION IN MICROCOLUMN SEPARATION TECHNIQUES AND

SAMPLING DEVICE

EXAMINER: Unknown

ART UNIT: Unknown

UNDER M.P.E.P. §708.02, VIII

Assistant Commissioner of Patents Washington, D.C. 20231

Sir:

In accordance with 37 CFR §1.102 and the procedure set forth in MPEP §708.02, section VIII, for accelerated examination procedure, Applicant requests, prior to examination, that the above-identified application be granted special status.

Applicant submits that the present petition and accompanying documents meet all of the requirements set forth at MPEP \$708.02, section VIII. Specifically, the applicant hereby submits the following:

- (a) the present petition to make special, accompanied by the fee set forth in 37 CFR 1.17(i) (\$130.00);
- (b) a Preliminary Amendment intended to limit the claims in the application to a single invention;

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- (c) a statement that a pre-examination search was made by applicant's agent, listing the field of search by class and subclass; and
- (d) a detailed discussion of the references deemed most closely related to the subject matter encompassed by the claims, which points out, with the particularity required by 37 CFR 1.111 (b) and (c), how the claimed subject matter is distinguishable over the references.

Applicant requests that, if the present request is defective in any respect, Applicant be given an opportunity to perfect the request, as provided in MPEP \$708.02, section VIII.

The Commissioner is authorized to charge any underpayment of fees herein (or credit any overpayment) to Deposit Account No. 04-0531. A duplicate copy of this paper is provided.

Respectfully submitted,

Date: <u>2-9-01</u>

Larry W. Thrower

Registration No. P47,994

CORRESPONDENCE ADDRESS

Customer No. 22918 (650) 324-0880

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Date: 2-9-01

By: Dabord Scockney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

Manz, et al.

SERIAL No.: Not yet Assigned

FILED: Concurrently Herewith

FOR: METHOD FOR CONTROLLING SAMPLE

INTRODUCTION IN MICROCOLUMN SEPARATION TECHNIQUES AND

SAMPLING DEVICE

Examiner: Unknown

ART UNIT: Unknown



INFORMATION DISCLOSURE STATEMENT ACCOMPANYING PETITION TO MAKE SPECIAL

Assistant Commissioner of Patents Washington, D.C. 20231

Sir:

The references listed on the enclosed Form PTO-1449 may be material to the examination of the above application. Copies of the references were previously submitted in the priority application. The Examiner is requested to make these references of official record in the present application.

The description below describes the general pertinence of each reference to the claimed invention. A detailed discussion of the most relevant prior art in view of the subject matter encompassed by the present claims is provided in the Preliminary Amendment enclosed herewith.

<u>Deml</u> describes a method for reproducible sampling of small quantities of sample for high-performance capillary electrophoresis. The method is based on the principle of the

splitter. The sample migrates electrophoretically in two electrical circuits and the splitting ratio is given by the ratio of the corresponding electric currents. However, there is no supply channel intersecting an electrolyte channel at a supply port. Thus, the sample volume cannot be defined in the electrolyte channel between two ports.

Harrison I describes a microfabricated electrophoresis device having a sample-injector formed by the intersection of two channels (Fig. 1). The sample is injected by dipping one end of a capillary into the sample reservoir and applying a voltage across the ends of the capillary. In the electric field the sample is transported electrokinetically and is injected at a T-junction into the channel system of the capillary electrophoretic device.

The sample volume in Harrison I is not defined geometrically. Instead, it is determined by the strength and time of the applied injection voltage. Thus, the sample volume according to Harrison I is not defined by a section of the electrolyte channel located between the supply port and the drain port, as is required by present Claim 19.

Harrison II discloses a microchannel device having first and second channels crossing at a point to form an intersection and connecting first and second reservoirs (channel 1) and third and fourth reservoirs (channel 2). Sample injection is achieved by drawing sample through the intersection by applying a voltage across reservoirs 1 and 2, followed by switching the applied potentials to reservoirs 3 and 4.

Harrison II does not, however, describe offsetting supply and drain channels along the electrolyte channel. Thus, the sample volume according to Harrison II is not defined by a

section of the elctrolyte channel located between the supply port and the drain port, as is required by present claim 19.

Verheggen discloses a sampling device for capillary isotachophoresis and capillary zone electrophoresis whereby the most essential feature of this device is the direct introduction of the sample solution into a part of the capillary tube by means of two feeders which extend perpendicular to the capillary tube. The arrangement of the two feeders off-set from each other along the longitudinal extension of the capillary tube is such that the sampling device has the shape of a capillary double T structure.

The device described in Verheggen et al. is distinguished from the claimed device in two aspects. First, Verheggen et al. fails to recognize the benefit of manipulating the supply and drain channel intersections with the electrolyte channel to form a geometrically defined sample volume between the supply and drain ports.

Second, Verheggen et al., at page 622, advises against the use of an electrokinetic technique to introduce the sample because such electrokinetic techniques do not result in the introduction of representative sample aliquots. Indeed, nearly the entire first paragraph of page 622 is devoted to discussing the disadvantages of using electrokinetic sample introduction in the disclosed apparatus. For example, the last three sentences describe an experiment where sampling was carried out with an electromigration technique. However, the experiment supported the conclusion that electrokinetic sampling techniques should not be used because the technique failed to introduce representative sample aliquots. Therefore, although Verheggen et al. recognizes the problem solved by the claimed invention, the reference offers no solution to the problem.

Byers describes a device having a first end, a second end, a first ion exchange medium extending from the first end to the second end, and a second ion exchange medium, which is in fluid communication with and has higher ion mobility than the first medium. The device, however, does not contain supply and drain channels that intersect an electrolyte channel. Thus, the device is unable to define a sample volume.

Pace describes an analytical separation device in which a capillary sized conduit is formed by a channel in a semiconductor device and the channel is closed by a glass plate. Electrodes are positioned in the channel to activate the motion of liquids through the conduit by electroosmosis.

Although the device described in Pace et al. includes a separation conduit and a sample channel, it lacks a drain channel. Without a drain channel to intersect the separation conduit, the sample volume cannot be defined geometrically.

Respectfully submitted,

Date: <u>2-9-01</u>

Larry W. Thrower

Registration No. P47,994

CORRESPONDENCE ADDRESS

Customer No. 22918 (650) 324-0880

INFORMATION DISCLOSURE CITATION Form PTO-1449 (Modified)

(Use several sheets if necessary)

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Manz, et al.

FILING DATE

GROUP

Concurrently Herewith Unknown

U.S. PATENT DOCUMENTS

*Examiner	Document	Date	Name	Class	Subclass	Filing Date
Initial	Number					If Appropriate
	4941958	7/90	Byers			
	4908112	3/90	Pace			

FOREIGN PATENT DOCUMENTS

Document Number	Date	Country	Class	Subclass	Translation

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

M. Deml, et al., Journal of Chromatography 320:159-165 (1985).
Harrison, et al., Analyt Chem <u>64</u> :1927-1932 (1992).
Harrison, et al, Sensors and Actuateers Blo (2):107-116 (1993)
Verheggen, et al., Journal of Chromatography 452:615-622, (1988).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

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Signature

Date

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

ANDREAS MANZ ET AL

SERIAL NO: 08/226,605

FILED: APRIL 12, 1994

FOR: METHOD FOR

CONTROLLING SAMPLE

INTRODUCTION IN MICROCOLUMN

SEPARATION TECHNIQUES AND SAMPLING DEVICE

Group Art Unit: 1102

Examiner:

Commissioner of Patents and Trademarks Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

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In accordance with 37 CFR 1.56, Applicants wish to call the Examiner's attention to the references cited on the attached form PTO-1449.

Copies of these references are enclosed herewith.

D9/780230

Attorney Docket No. 0225-0066.22

Transmittal of Continuation Patent Application for Filing

Certification Under 37 C.F.R. §1.10 (if applicable)

EL 530 373 662 US
"Express Mail" Label Number

February 9, 2001

Date of Deposit

I hereby certify that this application, and any other documents referred to as enclosed herein are being deposited in an envelope with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR \$1.10 on the date indicated above and addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231

Deborah H. Brockmeyer

(Print Name of Person Mailing Application)

(Signature of Person Mailing Application)

Also enclosed is a copy of the Search Report for the European counterpart of this application and a copy of each of the publications cited therein.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form.

Respectfully submitted,

George R. Dohmann Attorney for Applicants

Reg. No. 33,593

Ciba-Geigy Corporation 7 Skyline Drive Hawthorne New York 10532 (914) 785-7106 GRD/cmc Encl.

JUL 11 1994

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INFORMATION DISCLOSURE CITATION

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SERIAL NO. 08/226,605

APPLICANT ANDREAS MANZ ET AL

FILING DATE APRIL 12, 1994 GROUP 1102

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